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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------|-------------|----------------------|---------------------|------------------|
| 10/588,571 | 09/05/2008 | Alain H. Curaudeau | 249692001600 | 8305 |
| 25225 | 7590 | 01/27/2011 | EXAMINER | |
| MORRISON & FOERSTER LLP | | | JAGOE, DONNA A | |
| 12531 HIGH BLUFF DRIVE | | | | |
| SUITE 100 | | | ART UNIT | PAPER NUMBER |
| SAN DIEGO, CA 92130-2040 | | | 1619 | |
| | | | | |
| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | 01/27/2011 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

EOfficeSD@mofo.com

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/588,571 | CURAUEAU ET AL. |
| | Examiner | Art Unit |
| | Donna Jagoe | 1619 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-9, 11-14 and 20-22 is/are pending in the application.
 - 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 1-9, 11-14 and 20-22 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>10/30/06 and 6/28/10</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: ____ . |

DETAILED ACTION

Claims 1-9, 11-14 and 20-22 have been examined on the merits.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on Applications CA 2,457,214 and CA 2,470,403 filed in Canada on February 6, 2004 and June 9, 2004 respectively.

Information Disclosure Statement

The information disclosure statements filed on October 30, 2006 and June 28, 2010 have been reviewed and considered. See enclosed copies of PTO FORM 1449.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by QLT, Inc. (reference 10 from IDS dated 10/30/06).

QLT Inc. teaches treatment of acne (page 14, lines 22-26, claim 13 and 14) comprising administration of a photosensitizing agent, such as green porphyrins (page

3, line 30 through page 6) such as the preferred BPD-MA (verteporfin) (page 4, lines 15-18) and QLT0074 (lemuteporfin) (page 6, lines 4-7) and comprising administering a light energy to activate the photosensitizer at the target tissue (page 2, lines 10-23). The solubilizer of instant claim 1 is taught by QLT Inc in that the solubilizer aids in hydrophobic photosensitizers and are also penetration enhancers (page 9, line 30 to page 10, line 25). QLT Inc. teaches the preferred compositions to have a viscosity at 20°C of from about 50 cps to about 50000 cps (page 9, lines 24-25). Addressing the step of removing excess composition from the skin (instant claim 4) or wiping (instant claim 7), QLT Inc. teaches removing excess photosensitizer which might otherwise mask the target, preventing the activation energy from reaching the target (page 13, lines 7-11). Addressing instant claim 8, drawn to reduction of the total lesions by 30% or more, QLT, Inc. teaches administration of the same green porphyrin photosensitizers exposed to the same wavelength of energy for the same condition. The method wherein the steps are repeated until the total number of acne lesions has been reduced by 30% or more is considered to be inherent in the method of QLT, Inc.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over QLT Inc. (reference 10 from IDS dated 10/30/06) in view of Kalka et al. (J Am Acad Dermatol. Mar. 2000) (U).

QLT Inc. teaches treatment of acne (page 14, lines 22-26, claim 13 and 14) comprising administration of a photosensitizing agent, such as green porphyrins (page 3, line 30 through page 6) such as the preferred BPD-MA (verteporfin) (page 4, lines 15-18) and QLT0074 (lemuteporfin) (page 6, lines 4-7) and comprising administering a light energy to activate the photosensitizer at the target tissue (page 2, lines 10-23). The

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solubilizer of instant claim 1 is taught by QLT Inc in that the solubilizer aids in hydrophobic photosensitizers and are also penetration enhancers (page 9, line 30 to page 10, line 25).

Claims 13 and 14 are drawn to treatment of acne vulgaris comprising topically applying a green porphyrin and penetration enhancer to skin tissue and exposing the tissues to a light emitting diode device that emits red and blue light. Kalka et al. teach that diode lasers are employed to produce red light in the range of 770 to 850 nm (page 395, column 1) and teach that photodynamic management of dermatologic conditions is simplified by the accessibility of the skin to light application and leaves the option to use any light device with the appropriate spectrum corresponding to the absorption maximum of the photosensitizing compound (page 394, column 2). Further, QLT teaches use of any suitable light source to activate the photosensitizer (page 1, lines 9-14) and teach that photosensitizers generally absorb radiation in the range of from about 400 nm (about the range of blue light) to about 800 nm (about the range of red light) (page 3, lines 14-16).

A reference is good not only for what it teaches by the direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. *In re Opprecht* 12 USPQ2d 1235, 1236 (Fed. Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA 1976). A reference is not limited to working examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982). In light of the foregoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. § 103(a). From the teachings of the references, it is apparent that one of

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ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 1-9, 11, 12 and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over QLT Inc. (reference 10 from IDS dated 10/30/06) in view of Clement et al. Patent Application Publication US 2004/0166129 A1.

QLT Inc. teaches treatment of acne (page 14, lines 22-26, claim 13 and 14) comprising administration of a photosensitizing agent, such as green porphyrins (page 3, line 30 through page 6) such as the preferred BPD-MA (verteporfin) (page 4, lines 15-18) and QLT0074 (lemuteporfin) (page 6, lines 4-7) and comprising administering a light energy to activate the photosensitizer at the target tissue (page 2, lines 10-23). The solubilizer of instant claim 1 is taught by QLT Inc in that the solubilizer aids in hydrophobic photosensitizers and are also penetration enhancers (page 9, line 30 to page 10, line 25).

Clement et al. teach treatment of acne vulgaris comprising the use of retinoids (paragraph 6).

As stated in *In re Kerkhoven*, 626 F.2d 846, 205 USPQ 1069, at page 1072 (CCPA 1980):

It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is

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to be used for the very same purpose. In re Susi, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (CCPA 1960). As this court explained in Crockett, the idea of combining them flows logically from their having been individually taught in the prior art.

No claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Donna Jagoe /D. J./
Examiner
Art Unit 1619

January 17, 2011

/Robert A. Wax/
Supervisory Patent Examiner
Art Unit 1615